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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,417	02/28/2002	Donald J. McMichael	KCX-518D (17507D)	3208
22827	7590	04/27/2004	EXAMINER	
DORITY & MANNING, P.A. POST OFFICE BOX 1449 GREENVILLE, SC 29602-1449			BUI, LUAN KIM	
			ART UNIT	PAPER NUMBER
			3728	

DATE MAILED: 04/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/085,417

Applicant(s)

MCMICHAEL ET AL.

Examiner

Luan K Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5-7 and 13 is/are allowed.
- 6) ☒ Claim(s) 1-4, 8-10, 12 and 14-20 is/are rejected.
- 7) ☒ Claim(s) 11 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/15/04</u> . | 6) <input type="checkbox"/> Other: _____ |

1. The terminal disclaimer filed on 3/15/2004 has been reviewed and is accepted. The terminal disclaimer has been recorded. Therefore, all obviousness-type double patenting rejections have been obviated.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 12, 14-16 and 18-20 are finally rejected under 35 U.S.C. 102(b) as being anticipated by Ross et al. (5,318,543; hereinafter Ross'543). Ross'543 discloses a kit (10) for holding surgical articles comprising a tray (13) including a first planar surface having at least one first planar recess for holding surgical articles (17, 27), a second planar surface having at least one second planar recess for holding surgical article (23) and the second planar surface is vertically displaced from the first planar surface, and a third planar surface having at least one third planar recess for holding surgical articles (14, 21, 22, 24) or a removable container (20) and the third planar surface is vertically displaced from the first planar surface, a removable container (20) containing surgical articles (18, 19) disposed within at least one of the planar surfaces and a cover (11). Claim 12 does not require the second planar surface at different level than the third planar surface. Ross'543 further discloses at least one of the articles (14, 24, 26) having an elongated tapered end, at least one recess contains an introducer cannula (26) and at least one boss member extending upwardly through at least a portion of one of the articles (23).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 17 is finally rejected under 35 U.S.C. 103(a) as being unpatentable over Ross et al. (5,318,543; hereinafter Ross'543). Ross'543 discloses the kit as above having all the limitations of the claims except for the cover being formed from a permeable web. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the kit of Ross'543 so the cover is formed from a permeable web for sterilization.

6. Claims 1-4 and 8-10 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Ross et al. (5,318,543; hereinafter Ross'543) in view of Rudnick et al. (6,039,183; hereinafter Rudnick'183) and Harrison (5,392,918). Ross'543 discloses a kit (10) for holding surgical articles comprising a tray (13) having a plurality of planar surfaces (two planar surfaces) are offset vertically and at least one recess disposed in the at least one of the planar surfaces, a container (20) containing surgical articles (18, 19) disposed within at least one of the planar surfaces and a cover (11). Ross'543 further discloses the container (20) must be removed from the tray prior to access to the articles (17, 27) and other accessory articles such as a sterile drape, swabs, a packet of cotton and so forth could also be placed in the recesses if desired. Ross'543 also discloses the other claimed limitations except for the container comprises a base and a lid that define an interior space for retaining at least one accessory article. Rudnick'183 shows a

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package assembly/kit (20) comprising a cover (26) for a tray (22) having a plurality of recesses disposed therein, a container (24) including a base (44) and a lid (46) hingedly connected to the base and is adapted to fit at least partially within the tray. Harrison teaches a package assembly/kit (20) comprising a cover (28) for a tray (24) having recess and a container (26) disposed within the tray including a base (72) and a lid (70) define an interior space for holding an article. It would have been obvious to one having ordinary skill in the art in view of Rudnick'183 and Harrison to modify the container of Ross'543 so the container comprises a base and a lid that define an interior space for holding the articles for better protecting the articles. It would have been obvious to one having ordinary skill in the art in view of Ross'543 as modified to modify the container so the interior space is used to hold at least one accessory article because the selection of the specific articles for the container would have been an obvious matter of design choice inasmuch as the resultant structures will work equally well. As to claim 3, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the kit of Ross'543 as modified so the cover is formed from a permeable web for sterilization.

Allowable Subject Matter

7. Claims 5-7 and 13 are allowed.
8. Claims 11 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to all rejected claims have been considered but are deemed to be moot in view of the new grounds of rejection.

Applicant's arguments with respect to Ross'543 regarding the phrase "accessory article" recited in claim 1 are noted. They are not persuasive because the phrase as broadly recited is read on the articles in the container of Ross'543. However, the container of Ross'543 as modified is capable of holding at least one accessory article for the reason as stated above.

Applicant's arguments with respect to claim 12 are noted. They are not persuasive because claim 12 does not require the second planar surface at different level than the third planar surface.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luan K. Bui whose telephone number is (703) 305-5861. If in receiving this Office Action, it is apparent to Applicant that certain documents are missing from the record for example copies of references cited, form PTO-1449, form PTO-892, etc., requests for copies of such papers should be directed to TC 3700 Customer Service at (703) 306-5648.

Any inquiry of a general nature or relating to the status of this application should be directed to the Customer Service whose telephone number is (703) 872-9301. Facsimile correspondence for this application should be sent to (703) 872-9306 for Formal papers and After Final communications.

lkb
April 23, 2004

A handwritten signature in black ink, appearing to read 'Luan K. Bui', with a horizontal line underneath.

Luan K. Bui
Primary Examiner